

**TERRANEA CARES WELLNESS KIT- alcohol
Buzz Export Services Pty., Ltd.**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Terranea Cares Wellness Kit

Drug Facts

Active Ingredient

Ethyl Alcohol 75% (v/v)

Purpose

Antiseptic

Uses

To help reduce bacteria on the skin.

Warnings

- For external use only.
- Flammable. Keep away from fire or flame.

When using this product

- avoid contact with eyes.
- if contact occurs, rinse thoroughly with water.

Stop using and ask a doctor if

irritation or redness develops and lasts.

Keep out of reach of children

In case of accidental ingestion, get medical help or contact a poison control center immediately.

Directions

- Squeeze a significant amount in your palm and rub hands until full dry. No rinsing required.

Other Information

- Store below 110°f (43°C).

Inactive ingredients

Water (Aqua), Glycerin, Acrylates/C-10-30 Alkyl Acrylate Crosspolymer, Phenoxyethanol, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Aminomethyl Propanol.

Drug Facts

Active Ingredient

Ethyl Alcohol 75% (v/v)

Purpose

Antiseptic

Uses

- To help reduce bacteria on the skin.

Warnings

- For external use only.
- Do not dispose of wipes in flush toilets.

Flammable

- Keep away from fire or flame.

When using this product

- avoid contact with eyes.
- if contact occurs, rinse thoroughly with water.

Stop using and ask a doctor if

- irritation or redness develops and lasts.

Keep out of reach of children

- In case of accidental ingestion, get medical help or contact a poison control center immediately.

Directions

Apply to hands or surfaces.

No rinsing required.

Discard after use.

Other Information

- Store below 110°F (43°C).

- May discolor certain fabrics or surfaces.

Inactive ingredients

Aqua (Water), Glycerin, Polyquaternium-37, Melaleuca Alternifolia (Tea Tree) Leaf Oil.

Kit Label:



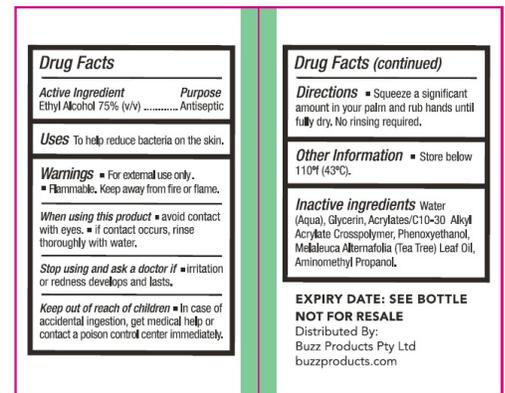
Package Labeling:69491-301-00



FRONT



BACK
PEEL AND REVEAL

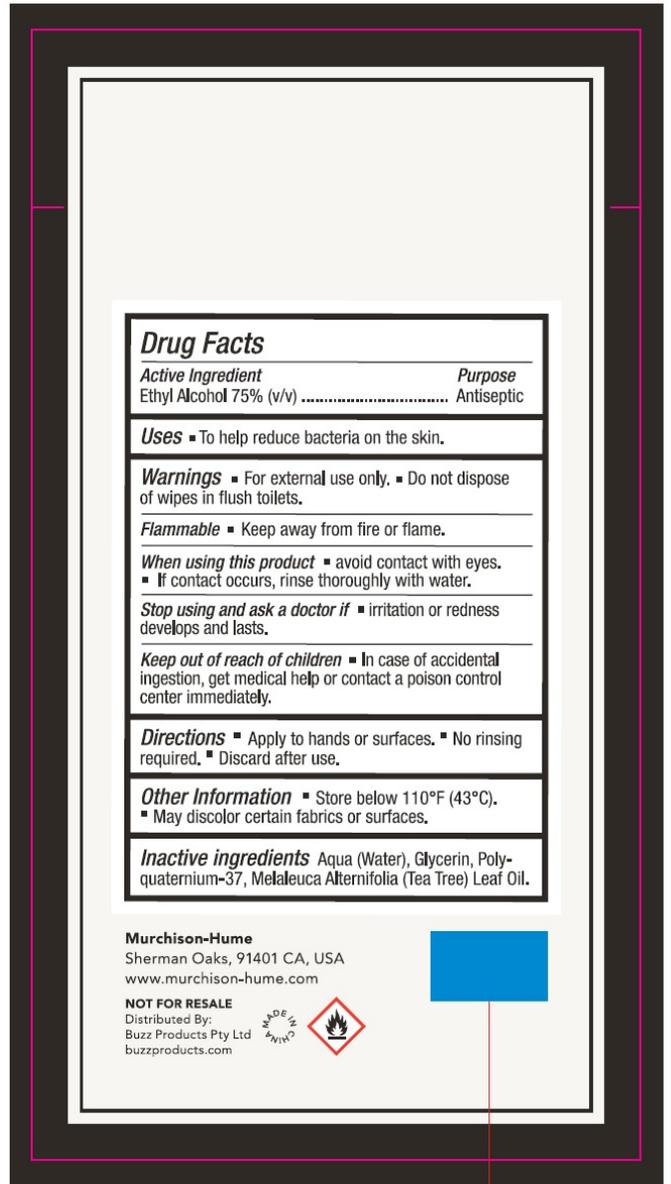


INSIDE
PEEL AND REVEAL

Package Labeling:69491-303-00



70mm



HD127
EXP: 12/2022

Batch code printed under drug facts table, aligned right.

TERRANEA CARES WELLNESS KIT

alcohol kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69491-304
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:69491-304-00	1 in 1 KIT	09/30/2020
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	20 mL
Part 2	1 PATCH	5 mL

Part 1 of 2

HAND SANITIZER WITH TEA TREE OIL 75% ALCOHOL

alcohol gel

Product Information

Item Code (Source)	NDC:69491-301
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69491-301-00	20 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/30/2020	

Part 2 of 2

MURCHISON-HUME SANITIZING WIPE WITH TEA TREE OIL 75% ALCOHOL

alcohol cloth

Product Information

Item Code (Source) NDC:69491-303

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.75 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69491-303-00	1 in 1 PACKAGE		
1		5 mL in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/30/2020	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/30/2020	

